UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 8

Application Number: 09/811,654
Filing Date: March 20, 2001
Appellant(s): LEVIN, GILBERT V.

Robert H. Berdo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7-31-2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-7 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim rejection – 35 U.S.C. 112(1)

> The following is a quotation of the first paragraph of 35 U.S.C. § 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is drawn to a method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose, dosage of 50 to 1,500 mg/kg to raise the HDL level in the mammal; wherein the tagatose is D-tagatose, L-tagatose, or a mixture of the two isomers.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by relevant identifying or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to show the applicant was in possession of the claimed genus. If the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlative. In the instant specification, the genus is that of tagatose. Applicant claims to be in possession of a method employing species of this genus, specifically L-tagatose or a mixture of the two in promoting cardiovascular health via elevation of HDL. Applicant's specification is based on a study using D-tagatose, exclusively for the elevation of HDL. There is no actual reduction to practice, support in the specification, nor nexus in the state of the art for the

use of L-tagatose or a mixture of D and L-tagatose to promote cardiovascular health via elevation of HDL levels in a mammal. The lone example presented on p. 2 of the specification seems to present a hypothetical treatment scenario that does not clearly lend support to whether applicant was in possession of the administration of L-tagatose or a mixture of the two isomers for a method of promoting cardiovascular health.

Claim Rejections - 35 U.S.C. 102(b)/103(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zehner et al., U.S. Patent No. 5,356,879.

Claims 1-5 are drawn to a method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose, dosage of 50 to 1,500 mg/kg to raise the HDL level in the mammal.

Claim 6 is drawn to the method of claim 1 wherein the tagatose is combined with a medication known to be useful in promoting cardiovascular health.

Zehner anticipates claims 1-5 as it teaches the administration of D-tagatose to a mammal, using a dosage within the claimed range, specifically 1 g/kg body weight (col.2, lines 45-60) to lower the rate of glycosylation end products that accumulate with age, that may be responsible for conditions such as atherosclerosis, capillary angiopathy and heart disease (col.3, lines 21 – col. 4, line 33; and col.1, lines 40-47). Mammals who have atherosclerosis would clearly be populations that would be in need of increasing levels of HDL; thus, per *In re Nowitzki*, the administration of tagatose by Zehner to reduce the occurrence of complications such as atherosclerosis due to accumulated glycosylation end products inherently anticipates applicant's intended use for increasing HDL and would clearly promote cardiovascular health.

Zehner however does not teach the combination of D-tagatose with a medication known to be useful in promoting cardiovascular health; however, it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose, *In re Kerkoven,* 626 F.2d 846, 205 USPQ 1069 (C.C.P.A. 1980).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal.

A person of ordinary skill in the art would have been motivated to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal given that the agents have been recognized in the prior art as being individually useful for conditions associated with low HDL levels.

(11) Response to Argument

35 USC 112(1) - Claim rejection, Claim 7

Applicants argue that on p.2 of the specification it clearly states that "an efficacious amount of.....D-tagatose, L-tagatose or a mixture of the two isomers may be

administered to a mammal". Applicant states that this is all that no more should be required to comply with 35 U.S.C. 112(1).

Applicant is reminded that an adequate written description or the possession element thereof is not satisfied by an intention, wish or plan for obtaining the claimed chemical invention (emphasis added), *Eli Lilly*, 119 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1711); as such, the statement of intention set forth in the specification, "...D-tagatose, L-tagatose or a mixture of the two isomers may be administered to a mammal to increase the HDL level of the mammal..", does not alone constitute an adequate written description. Moreover, the USPTO guidelines clearly state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure. As cited in the grounds of rejection, Applicant's specification is based on a study using D-tagatose (emphasis added), exclusively for the elevation of HDL. There is no actual reduction to practice, support in the specification, nor nexus in the state of the art for the use of L-tagatose or a mixture of D and L-tagatose to promote cardiovascular health via elevation of HDL levels in a mammal. The lone example presented on p. 2 of the specification seems to present a hypothetical treatment scenario that does not clearly lend support to whether applicant was in possession of the administration of L-tagatose or a mixture of the two isomers for a method of promoting cardiovascular health. To date, applicant has not provided a

specific response as to why the examiner's rationale for the written description rejection is in err given the factors cited supra.

35 USC 102(b)/103(a) - Claim rejections, Claims 1-6

Initially, applicant argues that the phrase "a method for promoting cardiovascular health in a mammal" is technically a part of the preamble; however, because it appears before the transition term "comprising", there should be no question in this case that it should be treated as a claim limitation. However, the phrase is still an intended use which actually does not affect the body of the claim which is actually administration of tagatose to raise the HDL level. In general, a preamble to a claim is not treated as a limitation if, for example, it merely sets forth the purpose or intended use of the invention. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). Furthermore, "an intended use or purpose usually will not limit the scope of the claim because such statements usually do no more then define a context in which the invention operates." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). Thus, "if the body of the claim sets out the complete invention, and the preamble is not necessary to give life, meaning and vitality to the claim, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1310 (Fed. Cir. 2002) **[**37]** (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1373-74 (Fed. Cir. 2001)). Assuming *arguendo* that the "promotion of cardiovascular health" provides antecedent

basis for elevation of HDL when used in conjunction with the term "comprising", it is clear that promotion of cardiovascular health merely sets forth a result of the invention in that it states an effect that occurs when the claimed method (elevation of HDL) is practiced.

Applicant asserts that the inherency argument per *Ex Parte Nowitzki*, 26 USPQ2d, 1389 (Board of Patent Appeals and Interferences 1993) is properly refuted because "a person practicing the invention disclosed by Zehner et al. would not necessarily and inherently promote cardiovascular health in the individual being treated. Further, the patient being treated for preventing the formation of advanced glycosylation end products by the method described by Zehner et al. would not necessarily be a patient in need of treatment for promoting cardiovascular health as required by the claims of this application". However, applicant's assertions do not confer with the teachings of the prior art of record; moreover, there are many decisions in addition to *Ex Parte Nowitzki* which have found that the discovery of "a previously unappreciated property of a prior art composition," "a scientific explanation for the prior art's functioning," or "newly discovered results of known processes directed to the same purpose" does not render the old composition new to the discoverer and such discoveries are not patentable because they are inherent in the prior art. See *Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999); Bristol-Myers, 246 F.3d at 1376.* Contrary to applicant's statements, the purpose of treating the glycosylation end products is to promote cardiovascular health by preventing the cardiac problems presented with these end products, particularly atherosclerotic cardiovascular disease. As cited supra,

mammals who have arteriosclerosis would clearly be populations that would be in need of increasing levels of HDL, thus it is unclear as to how applicant can regard these populations as being separate or distinct with regards to an inherency analysis. Applicant seeks to limit the teachings of Zehner to that of treating the aging process, but Zehner clearly teaches that cardiovascular complications associated with Diabetes Mellitus (DM) is also targeted with the use of D-tagatose in patients, therefore the assertion that Zehner is merely limited to treating the aging process is not convincing nor supported by the scope of the prior art teachings.

Applicant has not provided a response to the 103(a) rejection of claims 1 – 6, particularly claim 6, with the assumption that the inherency analysis is deficient or non-applicable to claims 1-5, therefore claim 6 falls as well. For the record the examiner repeats the rationale set forth in the grounds of rejection that although Zehner does not teach the combination of D-tagatose with a medication known to be useful in promoting cardiovascular health; it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose, *In re Kerkoven,* 626 F.2d 846, 205 USPQ 1069 (C.C.P.A. 1980).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal.

A person of ordinary skill in the art would have been motivated to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the

levels of HDL in a mammal given that the agents have been recognized in the prior art as being individually useful for conditions associated with low HDL levels.

For the reasons cited supra, the 35 U.S.C. 102/103 rejection of record is maintained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Howard Owens
November 3, 2003

Conferees:

James O. Wilson
Supervisory Patent Examiner
Tech Center 1600

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Tech Center 1600

Samuel Barts, Ph.D.
Primary Examiner
Tech Center 1600

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.
1300 19TH STREET, N.W.
SUITE 600
WASHINGTON,, DC 20036